

**REMARKS****Status of the claims:**

With the above amendments, claims 4 and 9 have been amended. Claims 1 and 3-10 are pending and ready for further action on the merits. No new matter has been added by way of the above amendments. Claim 4 has been amended by omitting members of a Markush group. The amendment to claim 9 is simply for form and is non-narrowing in scope. Reconsideration is respectfully requested in light of the following remarks.

**Rejections under 35 USC §112, second paragraph**

Claims 4 and 9 are rejected under 35 USC §112, second paragraph as allegedly being indefinite. The Examiner asserts that claim 4 is rejected for being indefinite because taurine and lecithin are not vitamins or analogues thereof. Applicants have followed the Examiner's suggestion and canceled "taurine" and the language that appears after the word "taurine". Applicants believe that with this amendment the rejection has been obviated. Withdrawal of the rejection is warranted and respectfully requested.

Regarding claim 9, the Examiner asserts that the word "which" should be changed to "wherein said agent". Applicants have amended the claim accordingly. Applicants believe that with this amendment

the rejection has been obviated. Withdrawal of the rejection is warranted and respectfully requested.

**Rejections under 35 USC §103**

Claims 1 and 3-10 are rejected under 35 USC §103(a) as being unpatentable over Lee '873 (US Patent Application No. 2002/0114873 A1). Applicants traverse.

The Examiner asserts that paragraph [0027] in Lee '873 discloses a herbal sauce comprising an aqueous extract of Acanthopanax Cortex (Siberian ginseng), Angelicae Gigantis Radix, and Cnidii Rhizoma.

First, Applicants, herein, submit a 37 CFR §1.131 declaration asserting that the instant invention was conceived of and reduced to practice prior to the effective date of Lee '873. As proof of this, Applicants attach a document showing Applicants' order letter for the priority document Korea 2001-26424. Please note that Korea is a WTO (World Trade Organization) member and was a member when section 531 of Public Law 103-465 of the Uruguay Round Agreements Act went into effect (i.e., January 1, 1996). Thus, the instant invention meets the requirements so that a declaration can be filed under 37 CFR §1.131(a). Moreover, because neither of the two conditions from 37 CFR §1.131(a) for exceptions is satisfied, Lee '873 is not available as prior art and cannot render obvious the

instant invention. For this reason alone, withdrawal of the rejection is warranted and respectfully requested.

Second, Applicants herein also differentiate the instant invention from Lee '873. Lee '873 discloses a herbal sauce comprising an aqueous extract of 'Acanthopanax Cortex' ('Siberian ginseng'), 'Angelican Gigantis Radix', and 'Cnidii Rhizoma'.

Attached to this response is a search from the internet showing that 'Siberian ginseng' falls under a different genus, Eleutherococcus (Acanthopanax), than does Korean ginseng (including wild or cultivated ginseng, i.e., Panax ginseng). 'Siberian ginseng' does not actually indicate ginseng, but rather 'ci wu jia'. Please see the attached web citation. Further, the 'Siberian ginseng' plant is a shrub of 1 to 3 meters tall, while the 'ginseng' plant is herbaceous. The uses of 'ginseng' and 'Siberian ginseng' overlap somewhat, but 'Siberian ginseng' is nevertheless a different and distinct plant with different active chemical components than the 'ginseng' plants (i.e., 'Siberian ginseng' comes from the genus eleutherosides, and 'ginseng' comes from the genus ginsenosides). Thus, because 'Siberian ginseng' is a completely different plant from 'ginseng', including 'wild ginseng', Applicants believe that Lee '873 cannot render obvious the instant invention. This is because Lee '873 simply fails to disclose the elements of the instantly claimed invention. For this

reason also, withdrawal of the rejection is warranted and respectfully requested.

With the above remarks and amendments, Applicants believe that the claims, as they now stand, define patentable subject matter such that passage of the instant invention to allowance is warranted. A Notice to that effect is earnestly solicited.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact T. Benjamin Schroeder (Reg. No. 50,990) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), Applicants respectfully petition for one (1) month extension of time for filing a response in connection with the present application. The required fee of \$55.00 is attached hereto.

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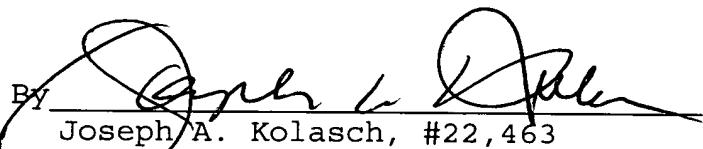
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If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachment(s): 37 CFR 1.131 Declaration by Mr. Won-Kyu Kim with both an English translation of the relevant parts of the order letter for Korean Patent Application No. 2001-26424 and a Korean document

Four attachments from web sites

(Rev. 02/12/2004)

## SPECIFICATION

### [Title of the Invention]

5 Food containing wild ginseng and preparation process thereof

### [Detailed Description of the Invention]

The present invention relates to a food prepared by adding sweeteners, stabilizing  
10 agents, preservatives, purified water and the like to a mixed powder of wild ginseng and  
herbs (containing 50% of wild ginseng).

(Omitted)

15 The mixed powder of wild ginseng and herbs as used herein contains 50% of wild  
ginseng powder and 50% of Lycii Fructus powder, Angelicae gigantis Radix powder and  
Cnidii Rhizoma powder.

Examples of the organic acid which can be used in the present invention include  
20 citric acid, malic acid, tartaric acid, fumaric acid and other available organic acids. These  
organic acids may be used alone or in combination with edible inorganic acids. The  
inorganic acids may be used alone or in a mixture of two or more kinds thereof.

Examples of the vitamins used in the present invention include one or more  
25 selected from vitamin C, vitamin B<sub>1</sub> (thiamine, thiamine hydrochloride, thiamine nitrate),  
vitamin B<sub>2</sub> (riboflavin, lactoflavin), nicotinic acid (niacin), vitamin B<sub>6</sub> (pyridoxine),  
pantothenic acid, biotin, choline, folic acid, vitamin B<sub>12</sub> (cobalamin), vitamin A, vitamin D,  
vitamin E or the like. The amount thereof may be in the range of a conventional amount  
of vitamin.

Examples of the preservative used in the present invention include sodium parahydroxybenzoate, methyl parahydroxybenzoate, propyl parahydroxybenzoate, ethyl parahydroxybenzoate, and others conventionally added to foods. They may be used alone or in combination. Their amount may be adjusted according to guidelines to apply food additives.

Examples of flavors used in the present invention include natural or artificial flavor such as orange flavor, lemon flavor, strawberry flavor and other fruit flavor, drink flavor, etc. They may be used in a conventional amount.

Water used in the present invention is conventional purified water or distilled water. Purified water is preferable.

Hereinafter, the present invention will be explained in more detail by the following examples and experimental examples.

**Example 1 – Wild ginseng concentrate by Samsung Pharm.**

|    |  |         |
|----|--|---------|
|    | Mixed powder of wild ginseng and herbs | 18.9%   |
| 20 | Cervi Parvum Cornu                     | 0.0114% |
|    | Cortex Acanthopanax                    | 0.114%  |
|    | Raw royal jelly                        | 0.02%   |
|    | Honey                                  | 10%     |
|    | Sucrose                                | 5%      |
| 25 | Concentrated glycerin                  | 2%      |
|    | Grain alcohol                          | 1%      |
|    | Sodium benzoate                        | 0.057%  |
|    | Xanthan gum                            | 0.04%   |
|    | Citric acid                            | 0.14%   |
| 30 | Ginseng flavor                         | 0.962%  |



|                |       |
|----------------|-------|
| Purified water | q. s. |
| Total          | 50 ml |

**Method:**

5           ① The mixed powder of wild ginseng and herbs, Cervi Parvum Cornu, and Cortex Acanthopanax were added to purified water. The mixture was extracted under heating at 90 ~ 95 °C for 3 hours, and the extract was filtered.

          ② The solution obtained in ① was transferred to a mixing tank, and thereto were added xanthan gum, honey, sucrose, glycerin, citric acid, and sodium benzoate. The  
10 mixture was stirred to the complete dissolution.

          ③ The solution obtained in ② was cooled to 30 °C, and raw royal jelly dissolved in grain ethanol and ginseng flavor were added thereto. The mixture was stirred and purified water was added thereto.

          ④ The solution obtained in ③ was stirred for 30 minutes, filtered through a 5-  
15 micron filter, and sterilized at 135 °C for 20 seconds. The solution was filled into a vial and the vial was sealed.

**Example 2 – Wild ginseng essence by Samsung Pharm.**

|    |  |        |
|----|--|--------|
| 20 | Mixed extract powder of wild ginseng and herbs | 0.3%   |
|    | Vitamin C                                      | 0.3%   |
|    | Thiamine nitrate                               | 0.01%  |
|    | Riboflavin                                     | 0.001% |
|    | Pyridoxine hydrochloride                       | 0.001% |
| 25 | Nicotinic amide                                | 0.01%  |
|    | Calcium pantothenate                           | 0.005% |
|    | Glycyrrhizae Radix extract powder              | 0.16%  |
|    | Lactose  | 0.213% |
|    | L-arginine                                     | 0.5%   |
| 30 | Cervi Parvum Cornu                             | 0.1%   |

|    |                       |        |
|----|-----------------------|--------|
|    | Taurine               | 0.01%  |
|    | Liquid fructose       | 10%    |
|    | Concentrated glycerin | 4%     |
|    | Sucrose               | 1%     |
| 5  | Citric acid           | 0.38%  |
|    | Sodium benzoate       | 0.058% |
|    | Xanthan gum           | 0.1%   |
|    | Stevioside (50%)      | 0.03%  |
|    | Ginseng flavor        | 0.5%   |
| 10 | Honey flavor          | 0.2%   |
|    | Herb flavor           | 0.2%   |
|    | Purified water        | q. s.  |

#### Method:

15       ① The mixed powder of wild ginseng and herbs, and Cervi Parvum Cornu were added to purified water, and the mixture was extracted under heating at 90 ~ 95 °C for 3 hours. The extract was filtered, and the filtrate was concentrated and dried at a low temperature.

20       ② Liquid fructose, glycerin, sucrose, citric acid, sodium benzoate, xanthan gum, taurine and stevioside were added to purified water of 90 ~ 95 °C, and the mixture was stirred to the complete dissolution.

      ③ The solution obtained in ② was cooled to 30 °C, and L-arginine, ginseng flavor, honey flavor, and herb flavor were added thereto. The mixture was stirred and filtered. The filtrate was sterilized at 135 °C for 20 seconds, and filled into a vial.

25       ④ The extract obtained in ①, vitamin C, vitamin B<sub>1</sub> nitrate, vitamin B<sub>2</sub>, vitamin B<sub>6</sub> hydrochloride, nicotinic amide, calcium pantothenate, Glycyrrhizae Radix extract powder, and lactose were added thereto. The mixture was added into the vial and the vial was sealed.

30       Experimental examples are as attached hereto.

## Analysis and Anti-fatigue Activities of Ginseng or Wild ginseng

(Omitted)

5

### Method and Materials

**Materials** – Components of mixed powder of wild ginseng and herbs were as shown in the following table. As control, ginseng was used in the same amount as wild ginseng.

10

Components of Wild Ginseng

| Components                      | Amounts   |
|---------------------------------|-----------|
| Wild ginseng powder             | 225 mg    |
| Lycii Fructus powder            | 74.97 mg  |
| Cnidii Rhizoma powder           | 75.015 mg |
| Angelicae gigantis Radix powder | 75.015 mg |
| Per 30 ml                       | 450 mg    |

15

**Experimental animals and breeding condition** - ICR mice of  $18 \pm 5$  g were bred in a breeding room of Sam Sung Pharmaceutical Ind. Co., Ltd. at a temperature of  $23 \pm 2$  °C, relative humidity of  $60 \pm 2\%$ , and illumination of 12 hrs/day. The animals were put into a mouse cage and provided with feed and water *ad libitum*.

20

**Construction of a swimming pool and measurement of swimming time** - Distilled water was filled in a transparent plastic square container of 15 cm×25 cm×20 cm with the height of 15 cm. While keeping the water temperature at 37 °C, the swimming time was measured. The experimental animals had been fasted for 12 hours and then, weighed. The animals were allowed to swim while hanging a lead wire of the 4% weight to the body weight on the neck. The finish time of swimming was defined at the time when the mice settled down with the two eyes' sinking for 5 seconds. The swimming time measurement were carried out under the same condition for control administered with physiological saline, test group '1' administered with ginseng, and test group '2' administered with wild ginseng.

25

**Weight-loaded forced swimming test** - Weight-loaded forced swimming test by Toshitsugu Moriura and David L., *et al.* was improved as follows. Distilled water was filled in a transparent plastic square container of 15 cm×25 cm×20 cm with the height of 15 cm. While keeping the water temperature at 37 °C, the swimming time was measured. The experimental animals had been fasted for 12 hours and then, weighed. The animals were allowed to swim while hanging a lead wire of the 4% weight to the body weight on the neck. The finish time of swimming was defined at the time when the mice settled down with the two eyes' sinking for 5 seconds. The experimental animals were divided into groups consisting of 7 animals, and administered for 1, 3, 5 and 7 days before experimentation. A test material was orally administered for 30 minutes before experimentation.

**Measurement of the content of a total saponin** - Samples of 1-2 g were added to 100 ml of water and transferred into a separatory funnel. Thereto was added 100 ml of ether, and the aqueous layer was extracted three times with 60 ml of water-saturated butanol. The combined extract was washed with 50 ml of water. The extract was dried and put into a weighed flask, and concentrated under reduced pressure (105 °C, 20 minutes). Then, it was left to cool in a desiccator and weighed. The content of a total saponin was calculated by the following formula:

$$\text{The content of a total saponin} = (A - B) / S \text{ (g)}$$

S: The initial weight of a sample

A: The weight of a flask containing extract concentrated under reduced pressure and dried (mg)

B: The weight of a flask when decreased by 0.25% or less compared with that before drying for 1 hour (mg)

**Measurement of Ginsenoside Rb<sub>1</sub>** - Samples of 3 g were taken and introduced into 50 ml of methanol. The mixture was filtered and the filtrate of 3 ml was developed on a pre-activated sep-pak. The sep-pak was washed with 10 ml of water and 15 ml of methanol,

and eluted with 10 ml of methanol. The eluted solution was used as a sample. The sample was analyzed by HPLC on C<sub>18</sub> reverse-phase column (Luna 10 $\mu$ ) [Flow rate: 0.6 ml/min, Mobile phase: 20% acetonitrile, Detector: UV detector (205 nm)].

5

## Results

**Evaluation of effect of the loaded weight on the swimming time and construction of anti-fatigue activity model** - Because a normal mouse can swim for 30 minutes or more, it takes a long time to observe the swimming time and is difficult to determine the finish time of swimming. Therefore, a certain weight was loaded in proportion to the body weight of a mouse, and the finish time of swimming was defined at a point of time when the two eyes sink down the surface of water for 5 seconds or more. As a result, the swimming time was shortened in a load-dependent way as set forth in the following Table 1. Therefore, it was concluded that it was the most ideal to test an anti-fatigue activity under the load of 4% weight to a mouse.

15

Table 1: Relation of Swimming time – Loaded weight in Mice

| Load (weight %) | The number of mice | Swimming time (min) |
|-----------------|--------------------|---------------------|
| 0               | 7                  | >30                 |
| 2               | 7                  | 20.31 $\pm$ 5.39*   |
| 3               | 7                  | 8.34 $\pm$ 2.29*    |
| 4               | 7                  | 1.10 $\pm$ 0.85*    |
| 5               | 7                  | 0.5 $\pm$ 0.06*     |

Each value represents the Mean $\pm$ S.D. of 7 mice. Load weight was determined by the rate of body weight. End-point of swimming time shows mouse eyes could not again return to the surface of water for over 5 seconds. Load-dependently different from control (\*, p<0.001)

20

**Anti-fatigue activity of ginseng and wild ginseng powder** - Using the above 4% weight-loaded mice, anti-fatigue activity of ginseng and wild ginseng were measured, and as a result, they were confirmed to have the anti-fatigue activity as follows (Fig. 1)

25

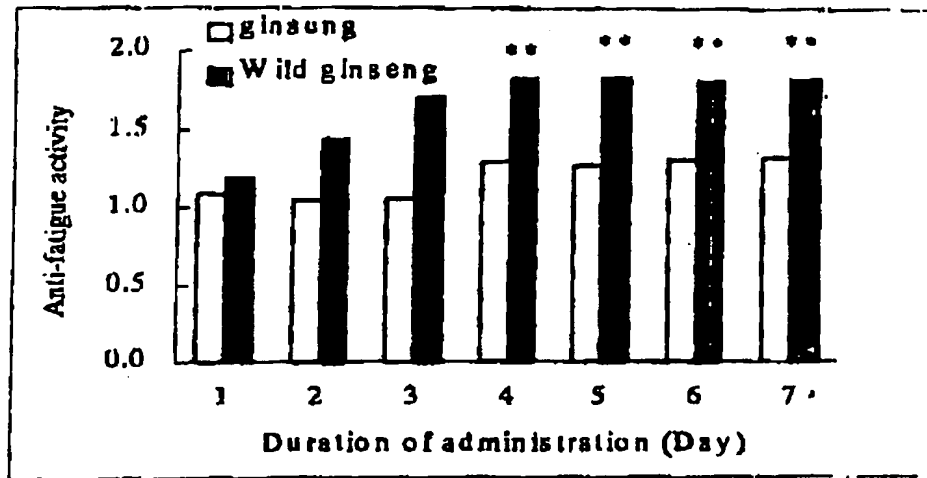


Fig. 1

- 1) Anti-fatigue activity = Swimming time of experimental group / Swimming time of control
- 2) We measured swimming time 30 min after administration of ginseng or wild ginseng.
- 3) The mean value  $\pm$  S.D. of 7 animals
- 4) Significantly different from control (\*\*,  $p < 0.01$ )

Content of a total saponin in ginseng and wild ginseng powder - As shown in Fig. 2,

wild ginseng has more total saponin than ginseng by two times.

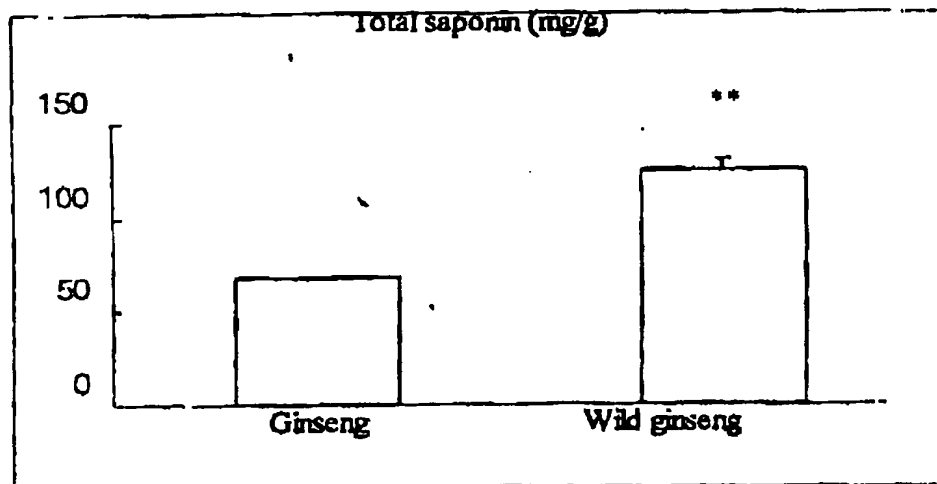


Fig. 2 The concentration of total saponin in ginseng or wild ginseng  
Significantly different from ginseng (\*\*,  $p < 0.01$ )

**Contents of ginsenosides Rb<sub>1</sub> and Rg<sub>1</sub>** - As shown in Fig. 3, the content of Rb<sub>1</sub> showed a significant difference between ginseng and wild ginseng powder.

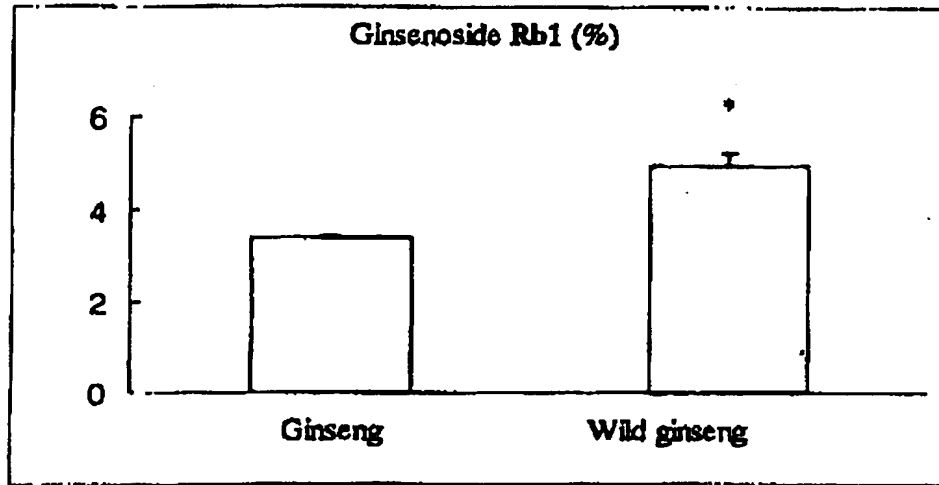


Fig. 3 The concentration of ginsenoside Rb<sub>1</sub> in ginseng or wild ginseng

Significantly different from ginseng (\*,  $p < 0.05$ )

### Conclusion & Discussion

Wild ginseng contains the total saponin by 2 times more than ginseng. As a result of analysis of ginsenoside Rb<sub>1</sub>, one of saponins, wild ginseng has a significantly, but not much, higher amount of ginsenoside Rb<sub>1</sub> than ginseng. From the result that wild ginseng has two-time more total saponin, but not much more ginsenoside Rb<sub>1</sub> than ginseng, wild ginseng is anticipated to have more other saponins, for example, ginsenoside Rb<sub>2</sub>, Rc, Rd, etc.

As a result of measurement of anti-fatigue activity, in the Experimental group administered with wild ginseng, a significant anti-fatigue effect was obtained in 4 days after administration. In the group administered with ginseng, an anti-fatigue effect could also be obtained, but was not significant.

From such results, wild ginseng is confirmed to have a higher anti-fatigue activity than ginseng, which may result from specific saponins contained in wild ginseng or ginseng.